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| 10/725,304 | 12/01/2003 | Lars Lindberg | P03,0559 | 2896 |

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| EXAMINER | |
|---|---|
| DEMILLE, DANTON D | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/725,304 | LINDBERG ET AL. | |
| | Examiner | Art Unit | |
| | Danton DeMille | 3771 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *15 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1 and 3-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

**1. Claims 1, 3-5, and 8 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kruse et al. US 5,957,839.**

**As to claim 1,** Kruse discloses a medical device (see fig. 1) comprising: a selectively permeable cuff (14). Although Kruse is silent on the cuff can be configured to be positioned in the trachea of a subject, however, Kruse in figure 1 clearly shows that his device has a tube (24, 26, 28) and a cuff (14) and the distal end of the tube containing the cuff (14) can be inserted into a person's trachea. Kruse teaches "Catheter 10 has a distal, intracorporeal end 12 which is placed within an organ or tissue of a patient's body by introduction through a body orifice, such as the nose, mouth, or rectum. Catheter distal end 12 has a distensible, inflatable, gas-permeable tonometry vessel 14 situated adjacent thereto" column 5, lines 57-62. Clearly the device of Kruse is not limited to any one intended use. There is no limit to the number of locations within the body the device can be used. One of the intended uses of the device is to be inserted into the mouth to be placed adjacent the desired organ or tissue. The device is intended for continuous monitoring of tissue gas composition and pH. The trachea and lungs are one of the possible locations for monitoring tissue gas composition and pH. Kruse does not state that the device cannot be used for such intended use. Therefore the tube of Kruse is capable of being placed in the trachea.

The end of the tube/catheter (24) has and end orifice (30) and side orifices (32). "Distal side orifices (32) are provided to obviate occlusion of all safety pressure relief lumen orifices by

contact with tissue during a procedure such as aspiration" column 6, lines 14-17. Clearly the tube/catheter (24) is capable of allowing the subject to respiration though the tracheal tube since it is designed for aspiration. Furthermore, Kruse in column 12 lines 2-4 discloses that the distal end of the tube/catheter is placed in the animal's stomach via the mouth, thus, suggest that the distal end containing cuff can be placed within other similarly sized passages such as a trachea when passed though the mouth of the subject. Kruse discloses a first tube (20) having a first end in fluid communication with an interior of the cuff (see fig. 1) and having an opposite, second end (connecting 56); a second tube (22) having a first end in fluid communication with the interior of the cuff (see fig. 1) and having an opposite, second end (connecting 56); a pumping device (52) connected to the respective second ends of the first and second tubes that circulates a fluid through the interior of the cuff (col. 8, lines 34 and 35); and said cuff comprising a membrane (col. 6, lines 30-33) that is selectively permeable to a specific substance ($CO_2$ gas or "particular gas to be measured", see col. 11 line 61) relative to said fluid, said membrane being disposed to allow transfer through said membrane of said substance from an exterior of the cuff to the interior of the cuff and an exterior of the cuff (since the membrane is permeable to gas, it will allow transfer of gas from the trachea ("exterior") to tube ("interior") via the membrane, see also col. 6, lines 30-33), and analysis unit (72) in fluid communication with said flow path (see fig. 1) tat analyzes said fluid with regard to content in said fluid of said substance that has mixed with said fluid from the exterior of the cuff (see col. 10 lines 63-68 and col. 11 lines 1-24). Therefore Kruse teaches all of the positive structural limitations. The only difference between the claims and Kruse is the intended use in the trachea. As set forth above, Kruse suggests such intended use since Kruse teaches the device can used to test any organ or tissue in the body by

introduction through the mouth. To any extent it is felt that there is some unclaimed limitation that is missing from Kruse it would have been obvious to one of ordinary skill in the art to modify Kruse such that it can be used in the trachea to test tissue within the trachea or lungs.

**As to claim 3**, Kruse discloses the analysis unit includes a calculation unit (76) that quantitatively determines an amount of said specific substance in said fluid relative to a predetermined normal amount (col. 10, lines 63-68, and col. 11, lines 1-24).

**As to claim 4,** Kruse discloses the medical device comprises a dosing unit (46) in fluid communication with said flow path that administers a dose of a medicament into said fluid (col. 7, lines 43-59).

**As to claim 5**, Kruse discloses wherein said analysis unit includes a calculation unit (76) that quantitatively determines an amount of said substance in said fluid relative to a predetermined normal amount (see col. 12 lines 30-40 where measured CO2 values are compared with a laboratory value/predetermined normal amount), dosing unit comprises at least one reservoir (a syringe inherently has a reservoir/space where gas will be held inside 46) containing at least one additive (substance introduced by the syringe) corresponding to said substance, said dosing unit including said additive from said reservoir in said medicament if said analysis unit determines that said amount of said substance in said fluid is below said predetermined normal amount (see col. 9 lines 53-57).

**As to claim 8,** Kruse discloses 58 that measures partial pressure of CO2 at any point in circuits 22, 42, 20 (see col. 10 lines 23-25), thus, when the dosing unit including said additive, the analyzing unit inherently analyzes the fluid with regard to content in said fluid of said substance that has mixed with said fluid from said exterior of the cuff and said medicament since

analyzing unit would analyzed total fluid content inside the tube in order to determine CO2 concentration.

**2. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kruse et al. and in view of Schultze US 4,141,364.**

**As to claim 6**, Kruse lacks wherein said cuff comprises at least one partition wall that partition the interior of said cuff into multiple chambers. However, Schultze teaches endotracheal tube cuff with multiple chambers (see figs. 7 and 8). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Kruse in order to provide multiple chambers because it is known in the art as taught by Schultze. Kruse further lacks each chamber having a first chamber tube with a first chamber tube end in fluid communication therewith and a second chamber tube with a first chamber tube end in fluid communication therewith, and wherein said first chamber tube has a second chamber tube end and said second chamber tube has a second chamber tube end in fluid communication with said pumping device for circulation of respectively separate fluids through the multiple chambers. However, since Kruse teaches at least two tubes are in communication with the cuff at a different location within the cuff, and one end of each tube is connected to a pumping device, it would have been obvious to have each tubes of Kruse connected to separate chambers of Schultze. It would have been further obvious to have multiple tubes (i.e. first and second chamber tubes of first and second chamber as claimed) connecting to the cuff because it has been held that mere duplicate of tubes only requires routine skills in the art. Furthermore, it would have been obvious to one of ordinary skill in the art to increase the number of tubes to expedite fluid circulation within the medical device.

**3. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kruse et al. and in view of Hanson et al. US 5,985,307 and in further in view of Walther et al. US 6,660,833 B1.**

**As to claim 7,** Kruse lacks wherein said membrane is permeable to at least one protein, as said substance, selected from the group of proteins consisting of SP-A, SP-B, SP-C and SP-D that are present in surfactant. However, Hansen teaches a balloon cuff membrane device that can be used to deliver therapeutic agent in the respiratory tree (see col. 2, lines 44 and 45) to treat a variety of disease syndromes (see col. 18, lines 55 and 56). Although Hansen's device is permeable to protein (i.e. antibody, see col. 26, line 55), Hansen however is silent on the claimed protein. However, Walther teaches respiratory distress syndrome therapy using peptide analogs of human SP-B that mimics human surfactant protein B (see abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Kruse in order to provide a membrane that allowed protein to pass though in the respiratory tree for the purposes of treating respiratory disease syndrome as taught by Hansen and further modify the membrane to be selective to SP-A for the purposes of treating respiratory distress syndrome as taught by Walther.

***Drawings***

The drawings were received on 7 December 2007. These drawings are objected to as containing new matter. The location of tube 22 has changed. Tube 22 now connects with the pumping device. This is not support in the specification. The specification states that the dosing tube 22 is intended to introduce a sufficient amount of therapeutically effective dose of proteins "further down to the lungs". As originally disclosed tube 22 achieved that. In the modified

version of figure 1 the tube connects with the pumping device and therefore cannot achieve the disclosed function of delivering the dose "further down to the lungs".

***Specification***

The amendment filed 7 December 2007 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is set forth in the above objection to the drawings.

Applicant is required to cancel the new matter in the reply to this Office Action.

***Response to Arguments***

Applicant argues that claim 1 has been amended to state that the first and second tubes proceed outside of the tracheal tube and the cuff. It is not clear how much weight can be given this argument since no such limitation is found in claim 1. Moreover there is no support in the specification for such a limitation. Applicant relies on figure 1 for support however, figure 1 is merely a schematic diagram and does not set forth any structural relationships. No structural relationships can be ascertained from figure 1.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Danton DeMille whose telephone number is (571) 272-4974. The examiner can normally be reached on M-F from 8:30 to 6:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu, can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published

applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

27 November 2008

/Danton DeMille/
Danton DeMille
Primary Examiner
Art Unit 3771